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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,096	07/26/2000	Robert M Umek	A-68271-2/RFT/RMS/RMK	8157

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EXAMINER	
CALAMITA, HEATHER	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/626,096	UMEK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Claims 60-69 are currently pending and under examination. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 60-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayyem et al. (WO 98/20162) in view of Shuber (USPN 5,633,134).

With regard to claim 60, Kayyem et al. teach a method of determining the identification of nucleotide(s) at a first detection position in a first domain of a target sequence, said target sequence comprising said first domain and a second domain, said method comprising:

a. providing an electrode with a covalently attached capture probe, wherein said capture probe has a sequence substantially complementary to said second domain of said target sequence (see p. 36 lines 10-22)

b. contacting said electrode with:

(i) said target sequence;

(ii) a first label probe substantially complementary to said first domain, comprising a first nucleotide at an interrogation position and a first electron transfer moiety (ETM) with a first redox potential (see p. 36 lines 10-22);

With regard to claim 63, Kayyem et al. teach an array of capture probes (see p. 36 lines 10-14, where the plurality of oligomers attached to a plurality of nucleic acids on a plurality of electrodes comprises the array).

With regard to claim 64, Kayyem et al. teach the first label probes contains a plurality of first ETMs (see p.36 lines 30-32).

With regard to claims 66-69, Kayyem et al. teach a ferrocene derivative (see p.41 line 21-24, where a substituted ferrocene is a ferrocene derivative and a transition metal ETM).

Kayyem et al. do not teach step (iii) a second label probe complementary to the first domain comprising a second nucleotide at said interrogation position.

With regard to claim 61, Kayyem et al. do not teach a third label probe complementary to the first domain comprising a third nucleotide at said interrogation position

With regard to claim 62, Kayyem et al. do not teach a fourth label probe complementary to the first target domain comprising a fourth nucleotide at said interrogation position.

Shuber teaches allele specific oligonucleotide hybridization using allele specific oligonucleotide probes.

With regard to claim 60, Shuber teaches multiple oligonucleotide probes with labels for determining nucleotides at the detection position (see abstract and col. 5 lines 13-21 and table 1, where the ASO are the labeled probes used to detect the mutations at the interrogation position)

With regard to claims 6, 62 and 65, Shuber teach multiple probes (see col. 5 table 1, which comprises the multiple labeled probes).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the ETM labeled oligonucleotides, as taught by Kayyem et al. with the multiple oligonucleotide probes for mutation detection, as taught by Shuber since Kayyem states, "In general electron transfer between electron donors and acceptors does not occur at an appreciable rate when the nucleic acid is single stranded, nor does it occur appreciably unless nucleotide base pairing exists in the double stranded sequence between the electron donor and acceptor in the double helical structure (see p. 9 lines 21-24)." An ordinary practitioner would have been motivated to use ETM labeled oligonucleotides, as taught by Kayyem et al. with the multiple oligonucleotide probes for mutation detection because Kayyem states that no electron transfer occurs unless nucleotide base pairing exists in the double stranded sequence between the electron donor and acceptor. This property is particularly advantageous for the detection of nucleotide mutations using the multiple probe methods as describe by Shuber in allele specific oligonulceotide hybridization.

Response to Arguments

3. Applicants' arguments with respect to the rejections over Kayyem and Schuber have been fully considered but they are not persuasive.

Applicants argue neither Kayyem nor Schuber teach a first and second labeled probes that are both complementary to the same domain. Applicants argue Kayyem teach a single probe complementary to two distinct sequences. This is not persuasive because as outlined in the rejection above Kayyem is not relied on for a teaching of two probes specific for one domain. Kayyem is relied on for teaching of a single probe complementary to a target domain and the use of ETMs. Shuber is relied on for teaching multiple oligonucleotide probes specific for one domain. As outlined in the rejection above, Shuber teach multiple oligonucleotide probes with labels for determining nucleotides at the detection position at col. 5

lines 13-21. Here Shuber describes ASOs (labeled probes) which are used to detect mutations at multiple interrogation positions.

Applicants argue the probes of Shuber are complementary to different genes or sequences or different mutation sites of the same genes/sequences. This is not persuasive because a probes that are complementary to different mutation sites of the same gene or same sequence. The same gene or same sequence is the same domain.

Applicants argue Neither Kayyem nor Shuber teach first and second probes having different nucleotides at the same interrogation position.

Applicants argue Kayyem teach a single probe complementary to two distinct sequences. This is not persuasive because as outlined in the rejection above, Kayyem is not relied on for a teaching of two probes specific for one domain. Kayyem is relied on for teaching of a single probe complementary to a target domain and the use of ETMs. Shuber is relied on for teaching multiple oligonucleotide probes specific for one domain. As outlined in the rejection above, Shuber teach multiple oligonucleotide probes with labels for determining nucleotides at the detection position at col. 5 lines 13-21. Here Shuber describes ASOs (labeled probes) which are used to detect mutations at multiple interrogation positions.

Summary

4. No claims allowed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc

TERESA E. STRZELECKA, PH.D.
PRIMARY EXAMINER

Teresa Strzelecka
7/20/06